

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 2

### REMARKS

The previous rejection of the claims based on U.S. Patent No. 5,545,211 to An et al. has been withdrawn. This determination is gratefully acknowledged.

Independent claim 26 stands rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 2,780,274 to Roberts et al. (hereinafter "Roberts"). This determination is respectfully traversed.

It has been previously submitted that Roberts fails to anticipate the present claims as claim 26 clearly recites an intraluminal device including a tubular stent formed of wire defining a plurality of nested wire waves wherein the nested wire waves inhibit tissue ingrowth between the waves and a cover extending along the length of the stent further inhibiting tissue ingrowth.

Initially, it is noted that the preamble of claim 26 clearly limits the claim to an intraluminal device. Quite simply, the Roberts device is not an intraluminal device. The Examiner contends that the preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness on the introductory clause.

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 3

Assuming, *arguendo*, the correctness of the Examiner's position, the preamble of claim 26 is tied directly to the remainder of the claim and must be viewed in combination therewith. The preamble recites an intraluminal device. The body of the claim further recites a tubular stent with nested waves for inhibiting tissue ingrowth and a cover further inhibiting tissue ingrowth. Thus, the intraluminal recitation in the preamble is significant in that it limits the claim to a device which is put within a lumen so that the elements recited in the body operate as claimed in an intraluminal fashion. Thus, in the present instance, the preamble is a limitation of the claim which helps define the scope of the present invention. Moreover, since it is not found in the Roberts reference, Roberts cannot anticipate the claim.

Additionally, notwithstanding the preamble limitation, Roberts does not anticipate the claim with respect to limitations contained in the body of claim 26. First and foremost, Roberts is not a stent. A stent is generally and conventionally defined as a small tube that is used to treat narrowed or weakened arteries in the body. Meridian Webster's Medical Dictionary defines a stent as a short, narrow tube inserted into the lumen of an anatomical vessel, especially to keep the previously blocked passageway open. Under no reasonable interpretation of the Roberts reference could the device shown in Roberts meet the definition of a stent.

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 4

Still further, claim 26 specifically recites a construction of the stent which inhibits tissue ingrowth between the waves of the stent. The present invention does this by providing wire waves which are nested. While Roberts suggests that its wire bands can be positioned side-by-side and in some type of nested relationship, there is no disclosure whatsoever of nesting the wire waves to inhibit tissue ingrowth therethrough. Roberts specifically discloses employing the wire bands to provide reinforcement to the cover. Again, Roberts not being a medical device, does not in any respect, clearly disclose employing the nested wire waves to prevent anything, let alone tissue, from migrating through the body of the stent.

In applying the Roberts reference, the Examiner concludes that:

While the device is not intended for intraluminal applications, the resulting structure would provide the function of not allowing free tissue ingrowth through the cover and through the wire. (Office Action at page 4).

However, as noted above, the express purpose of the wire waves of Roberts is to reinforce the cover. There is absolutely no disclosure of employing the wire waves to prevent anything from passing through the waves. Thus, the Roberts device and the stent of the present invention have completely different purposes.

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 5

In order for a reference to be anticipatory, the reference must either expressly or inherently disclose every limitation set forth in the claim and such elements must be argued as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 U.S.P.Q. 2d 1913 (Fed. Cir. 1989). As noted above, Roberts fails to meet this standard. Accordingly, claim 26 and, therefore, the claims which depend therefrom are not anticipated by Roberts. It is, therefore, respectfully submitted that the Examiner's rejection of the claims based on Roberts is obviated.

Independent claim 26 also stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,554,181 to Das in view of U.S. Patent No. 5,330,500 to Song. This determination is respectfully traversed.

The Examiner contends that Das discloses an elongate tubular stent with nested wire waves having various amplitudes. The Examiner specifically cites column 6, lines 45-54, along with Figure 1 of Das as allegedly disclosing nested wire waves. The passage referred to by the Examiner recites as follows:

FIGS. 1-3 show the construction of an embodiment of the stent of the present invention. The stent 1 is a coil 4 having a generally cylindrical shape with an open lumen 6. That is, as shown in FIG. 3, the stent 1 has a circular cross section with an open central portion or lumen 6. A continuous wire 8 can be used to form the coil 4 such that the coil has successive windings (or loops) 10 and is prevented from stretching in its longitudinal axis. Any two

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 6

adjacent successive windings 10 (or first 10A and second 10B windings) are connected and restrained from stretching longitudinally by an interconnecting portion or strip 12 of the wire.

Nowhere in the above passage, nor in Figure 1, does Das disclose a nested wire wave as recited in claim 26. Nesting is described in the present specification at page 6, line 26 through page 7, line 6, as a stent having wire waves where specifically the peaks of the longitudinally adjacent windings are linearly aligned so that each wave is stacked or nested within the next adjacent wave. The benefits of such an arrangement are more fully described in the specification at page 7, line 7, through page 8, line 23. The nesting of the wire waves provides a wire with greater wire density while maintaining flexibility.

As clearly defined and used in the specification of the present invention, Das does not disclose or even suggest nesting of its wire waves.

The Song reference fails to meet the deficiencies of the Das reference as Song also fails to disclose a nested stent. Therefore, either taken alone or in combination, Das and Song fail to disclose, teach or suggest the limitations set forth in independent claim 26. As such, claim 26 and the claims which depend therefrom are believed to be patentably distinct over the cited combination. Reconsideration, therefore, is respectfully solicited.

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 7

Claims 26-38 are further rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1-10, 18, 26, 29, 32, 72 and 81 of U.S. Patent No. 6,319,277 and claim 10 of U.S. Patent No. 5,575,816. In an effort to expedite prosecution of the application, submitted herewith are Terminal Disclaimers which are used to overcome the double-patent rejections presented herewith.

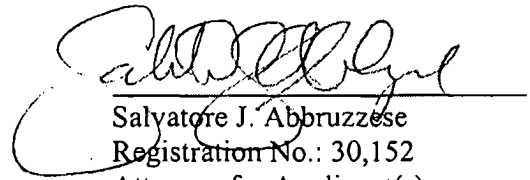
Having responded in full to the present Office Action, it is respectfully submitted that the application, including claims 26-37, is in condition for allowance. Favorable action thereon is respectfully solicited.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Applicant: Rudnick et al.  
Application Serial No.: 10/775,536  
Filing Date: February 10, 2004  
Docket No.: 760-84 CON 4 RCE  
Page 8

Should the Examiner have any questions regarding this response, the undersigned would be pleased to address them by telephone.

Respectfully submitted,



Salvatore J. Abbruzzese  
Registration No.: 30,152  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Sy osset, New York 11791  
(973) 331-1700